



Commercial/Healthcare Exchange PA Criteria

Effective: December 9th, 2021

Prior Authorization: Lybalvi

Products Affected: Lybalvi (Olanzapine and Samidorphan) Tablet

Medication Description: Lybalvi is a combination of olanzapine (an atypical antipsychotic) and Samidorphan (an opioid antagonist). The exact mechanism of action of olanzapine is unknown; however, its efficacy in the treatment of schizophrenia and bipolar I disorder may be mediated through a combination of dopamine and serotonin type 2 (5-HT₂) antagonism. The mechanism of Samidorphan is hypothesized to be mediated through opioid receptor antagonism. Samidorphan binds to the mu-, kappa-, and delta-opioid receptors, and functions as a mu-opioid receptor antagonist with partial agonist activity at kappa- and delta-opioid receptors

Covered Uses: Lybalvi is indicated for the treatment of 1) schizophrenia in adults; and 2) bipolar I disorder in adults for the acute treatment of manic or mixed episodes as monotherapy and as an adjunct to lithium or valproate, as well as for maintenance monotherapy treatment.

Exclusion Criteria: Lybalvi is **contraindicated in patients who are using opioids or who are undergoing acute opioid withdrawal**. In patients who use opioids, delay initiation of Lybalvi for a minimum of 7 days after last use of short-acting opioids and 14 days after last use of long-acting opioids. If Lybalvi is given with lithium or valproate, the contraindications regarding use of these agents also apply.

Required Medical Information:

1. Diagnosis
2. Medical History
3. Previous therapies tried and failed

Age Restrictions: Age \geq 18 years

Prescriber Restrictions: Lybalvi is prescribed by or in consultation with a psychiatrist or a physician who specializes in mental health care

Coverage Duration: 12 months

Other Criteria:

1. **Bipolar Disorder and Schizophrenia.** Approve for 12 months if the patient meets all of the following:
 1. Diagnosis of bipolar I disorder or schizophrenia; **AND**
 2. Age \geq 18 years; **AND**
 3. Patient does not have a known opioid use disorder or is dependent on opioids for a chronic health condition; **AND**
 4. Failure of a 4-week trial of one additional preferred atypical antipsychotic (e.g., aripiprazole, ziprasidone, risperidone) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated; **AND**
 5. Trial of generic olanzapine demonstrated positive response, but unacceptable weight gain while on therapy

January 2021



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References:

1. Lybalvi™ tablets [prescribing information]. Waltham, MA: Alkermes; May 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/9/2021